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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0355]

2-11-05
2-16-05
J. O. O.

Scientific Considerations Related to Developing Follow-On Protein Products; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until March 16, 2005, the comment period for the notice that appeared in the **Federal Register** of August 16, 2004 (69 FR 50386). In the notice, FDA announced a public workshop on scientific and technical considerations related to the development of follow-on protein pharmaceutical products and plans to develop draft guidance and requested comments related to developing and approving follow-on protein pharmaceutical products. The agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: Submit written and electronic comments by March 16, 2005.

ADDRESSES: Submit written comments on scientific topics related to follow-on protein products to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Keith Webber, Center for Drug Evaluation and Research (HFD-121), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852, 301-443-5089, e-mail: keith.webber@fda.gov, or Chris

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Joneckis, Center for Biologics Evaluation and Research (HFM-1), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20892, 301-827-2000, e-mail: *christopher.joneckis@fda.gov*.

SUPPLEMENTARY INFORMATION:

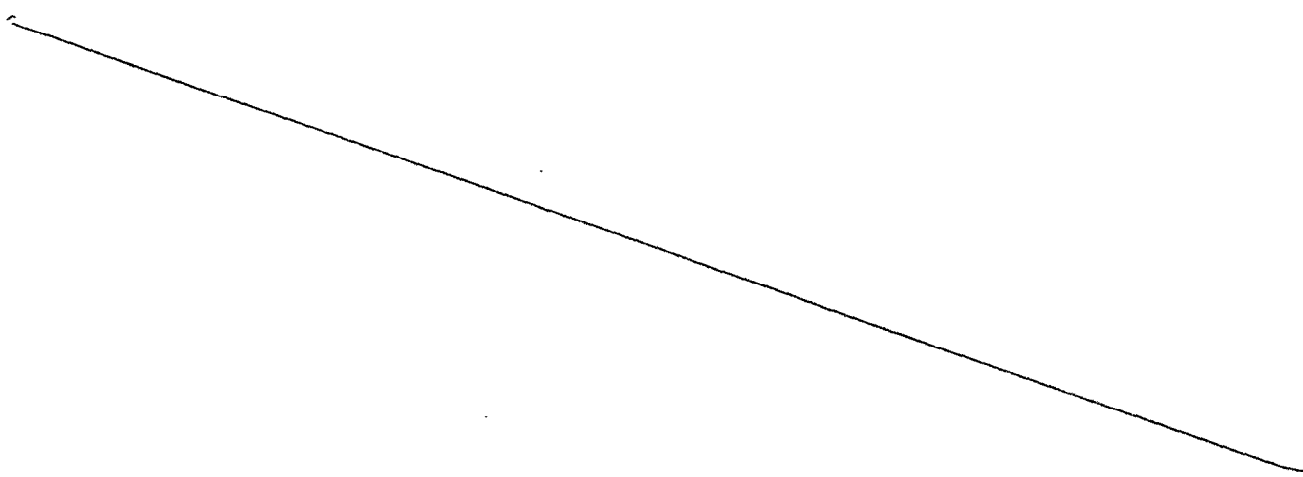
I. Background

In the **Federal Register** of August 16, 2004 (69 FR 50386), FDA published a notice with a 90-day comment period to request comments on the scientific and technological perspectives of manufacturers, academia, and other interested persons to determine the state of the science as it relates to protein characterization, production, and assessment of similarity.

The agency has received requests for an extension of the comment period for the notice. In response to these requests, FDA has decided to reopen the comment period for the notice for an additional 30 days, until March 16, 2005.

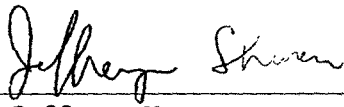
II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on this document. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments are available for public



examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 2/11/05
February 11, 2005.



Jeffrey Shuren,
Assistant Commissioner for Policy.



[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

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